

§ 872.3960

fossa prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[59 FR 65478, Dec. 20, 1994, as amended at 63 FR 71746, Dec. 30, 1998]

§ 872.3960 Mandibular condyle prosthesis.

(a) *Identification.* A mandibular condyle prosthesis is a device that is intended to be implanted in the human jaw to replace the mandibular condyle and to articulate within a glenoid fossa.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* (1) Except as described in paragraph (c)(2) of this section, a PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any mandibular condyle prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before March 30, 1999, been found to be substantially equivalent to a mandibular condyle prosthesis that was in commercial distribution before May 28, 1976. Any other mandibular condyle prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

(2) No effective date has been established of the requirement for premarket approval for any mandibular condyle prosthesis intended to be implanted in the human jaw for temporary reconstruction of the mandibular condyle in patients who have undergone resective procedures to remove malignant or benign tumors, requiring the removal of the mandibular condyle. See § 870.3 of this chapter.

[59 FR 65478, Dec. 20, 1994, as amended at 63 FR 71746, Dec. 30, 1998]

§ 872.3970 Interarticular disc prosthesis (interpositional implant).

(a) *Identification.* An interarticular disc prosthesis (interpositional implant) is a device that is intended to be an interface between the natural articulating surface of the mandibular condyle and glenoid fossa.

(b) *Classification.* Class III.

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(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any interarticular disc prosthesis (interpositional implant) that was in commercial distribution before May 28, 1976, or that has on or before March 30, 1999, been found to be substantially equivalent to an interarticular disc prosthesis (interpositional implant) that was in commercial distribution before May 28, 1976. Any other interarticular disc prosthesis (interpositional implant) shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[59 FR 65478, Dec. 20, 1994, as amended at 63 FR 71746, Dec. 30, 1998]

§ 872.3980 Endosseous dental implant accessories.

(a) *Identification.* Endosseous dental implant accessories are manually powered devices intended to aid in the placement or removal of endosseous dental implants and abutments, prepare the site for placement of endosseous dental implants or abutments, aid in the fitting of endosseous dental implants or abutments, aid in the fabrication of dental prosthetics, and be used as an accessory with endosseous dental implants when tissue contact will last less than 1 hour. These devices include drill bits, screwdrivers, countertorque devices, placement and removal tools, laboratory pieces used for fabrication of dental prosthetics, and trial abutments.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

[65 FR 60099, Oct. 10, 2000]

Subpart E—Surgical Devices

§ 872.4120 Bone cutting instrument and accessories.

(a) *Identification.* A bone cutting instrument and accessories is a metal device intended for use in reconstructive oral surgery to drill or cut into the upper or lower jaw and may be used to